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10/574,337	05/09/2006	Seong Hwan Cho	1751-0400	8934

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ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,337	CHO ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds Draper	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are presented for examination.

Applicant's Amendment filed November 18, 2010 has been received and entered into the present application.

Claims 1-16 remain pending and under examination. Claims 1, 13 and 16 are amended.

Applicant's arguments, filed November 18, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claim 1 is directed to a sustained-release formulation comprising (a) a sustained-release core comprising a mixture of an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions; (b) an enteric film coating layer coated on the sustained-release core; and (c) an active ingredient containing film coating layer coated on the enteric film coating layer and

comprising the active ingredient and a hydrophilic polymer for film coating, wherein the formulation is a three-layer containing tablet.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitations directed to (1) wherein the sustained release formulation is a three-layer containing tablet (claim 1) or (2) that the sustained-release core comprises a mixture of an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions (claim 1).

Applicant's specification at p.9-11 (and throughout the specification as a whole) describes the claimed sustained-release formulation in the form of a tablet, wherein the tablet contains various layers, including (i) the core layer comprising the active ingredient and polymer with erosion and swelling property in mammalian intestinal secretions, (ii) the enteric film coating layer coated onto the core layer, (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer, and optionally (iv) an additional outer coating layer coated on the active ingredient-containing film coating layer.

While such teachings have been fully and carefully considered, it is noted that such disclosure fails to be supportive of the concept of the instantly claimed sustained release formulation in a "three-layer containing tablet", wherein the tablet contains three layers or more (as evidenced by the phrase "three-layer containing" tablet). Thus disclosure that the instantly claimed composition may contain three layers (i.e., (i) the core layer comprising the active ingredient and polymer with erosion and swelling property in mammalian intestinal secretions, (ii) the enteric film coating layer coated onto the core layer, and (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer) or possibly four layers (i.e., (i) the core layer comprising the active ingredient and polymer with erosion and swelling property in mammalian intestinal secretions, (ii) the enteric film coating layer coated onto the core layer, (iii) an active ingredient-containing film coating layer coated on the enteric film coating layer,

and (iv) an additional outer coating layer coated on the active ingredient-containing film coating layer) fails to provide clear written support to now claim that the instant sustained release composition may contain any number of layers provided it has at least three layers (e.g., 10 layers, 30 layers, etc.). This is a clear broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear from what is disclosed in the originally filed specification and claims that Applicant was not in possession of the concept of formulating the claimed sustained-release composition into a tablet with any number of layers (i.e., "three-layer containing", which is interpreted as at least three or more), but rather was solely in possession of the concept of a tablet form comprising the instantly claimed sustained release composition that appears to have only three or four layers.

Applicant discloses at p.10 of the instant specification that, "The sustained-release core contained in the sustained-release formulation of the present invention can be prepared by directed compression or compaction-granulation. In the case of using direct compression, the sustained-release core can be prepared in such a manner than an active ingredient, a swellable polymer (e.g., Methocel K4M CR Premium), a direct compression diluent (e.g., Avicel PH102), and a disintegrating agent (e.g., Primojel) are mixed and then a lubricant such as magnesium stearate is further added thereto, followed by tabletting. In the case of using compaction-granulation, the sustained-release core can be prepared in such a manner that an active ingredient, a swellable polymer (e.g., Methocel K4M CR Premium), a diluent (e.g., Avicel PH01), a disintegrating agent (e.g., L-HPC), a binder (e.g., HPC-L), and a lubricant (e.g., magnesium stearate) are mixed, followed by granulation with a compaction granulator (e.g., roller compacter), screening through an about 20-mesh screen, and tabletting."

While such teachings have been fully and carefully considered, it is noted that such disclosure fails to be supportive of the concept of the instantly claimed sustained release formulation in which the sustained release core comprises a "mixture" of an active ingredient and a polymer having erosion and

swelling property in mammalian intestinal secretions as instantly claimed. This disclosure that the instantly claimed formulation may contain a core of the active ingredient, a swellable polymer, a direct compression diluent and a disintegrating agent that are mixed when direct compression is used to form the sustained-release core or may contain the active ingredient, a swellable polymer, a diluent, a disintegrating agent, a binder and a lubricant that are mixed when compaction-granulation is used to form the sustained-release core fails to provide clear written support to now claim that the sustained release core contains a mixture of only the active ingredient and the polymer with erosion and swellable properties in mammalian intestinal secretions when the other components required for such a mixture and/or the manner in which the core is formed (i.e., direct compression, compaction-granulation, etc.) are not clearly required by the claims. This is a clear broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear from what is disclosed in the originally filed specification and claims that Applicant was not in possession of the concept of a sustained-release formulation containing a sustained-release core comprising a mixture of an active ingredient and a polymer having erosion and swelling properties in mammalian intestinal secretions, but rather was solely in possession of the concept of a sustained-release formulation comprising a sustained-release core that contains the active ingredient, a swellable polymer, a direct compression diluent and a disintegrating agent that are mixed when direct compression is used to form the core or may contain the active ingredient, a swellable polymer, a diluent, a disintegrating agent, a binder and a lubricant that are mixed when compaction-granulation is used to form the core.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of in haec verba) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably

convey to one skilled in the relevant art that Applicant had possession of the concepts of (1) wherein the sustained release formulation is a three-layer containing tablet (claim 1) or (2) that the sustained-release core comprises a mixture of an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions (claim 1).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda et al. (U.S. Patent Application Publication No. 2003/0147948; 2003), already of record, for the reasons of record set forth at p.5-8 of the Office Action dated August 18, 2010, of which said reasons are herein incorporated by reference.

Newly amended claim 1 remains properly included in the instant rejection because Shinoda et al. teaches that the sustained-release particles are formulated by layering the drug onto a core particle (i.e., commercial crystalline cellulose particles, crystalline lactose, granular sugar, sodium chloride, silicon dioxide, etc.) using a binder such as hydroxypropyl methylcellulose (i.e., which meets Applicant's claimed "polymer having erosion and swelling property in mammalian intestinal secretions" as recited in instant claims 1 and 3-6) (see, e.g., p.8, para.[0074]), which is understood to meet Applicant's newly added claim limitation directed to the sustained-release core comprising "a mixture of" an active ingredient and a polymer having erosion and swelling properties in mammalian intestinal secretions because the interaction of the active drug (layered onto a core particle) with the applied binder (i.e., hydroxypropyl methylcellulose) at the interface of the two components creates a molecular "mixture" of the two elements. Furthermore, there is no requirement, either in the claims or the originally filed specification, that the "mixture" as instantly claimed is a homogenous mixture as alleged by Applicant (see, e.g., p.8 of the Remarks filed November 18, 2010).

Newly amended claim 1 now also states that the claimed sustained-release formulation is a "three-layer containing tablet". This is met by Shinoda et al., who discloses that the sustained-release particles are formulated by layering the drug onto a core particle (i.e., commercial crystalline cellulose particles, crystalline lactose, granular sugar, sodium chloride, silicon dioxide, etc.) using a binder such as hydroxypropyl methylcellulose (i.e., which meets Applicant's claimed "polymer having erosion and swelling property in mammalian intestinal secretions" as recited in instant claims 1 and 3-6), which therein constitutes a first layer, wherein the particle is then further coated with a polymer substance, such as, inter alia, an enterosoluble polymer substance (i.e., which is defined at para.[0055] of Shinoda et al. to include enterosoluble acrylic acid copolymers, such as methacrylic acid-ethylacrylate copolymer) (p.8, para.[[074]), which therein constitutes a second layer. Shinoda et al. further discloses that a polymer substance with drug may be layered onto the particles to make a sustained release particle, wherein

Shinoda et al. teaches that substances, such as, inter alia, polyvinyl alcohol may be mixed with the polymer components (i.e., which meets Applicant's part (c) of the claimed formulation, wherein polyvinyl alcohol is the hydrophilic polymer for film coating; p.6, para.[0057]) and the particles may then be given enterosoluble function by coating with an enterosoluble polymer base as necessary (of which Shinoda et al. explicitly teaches methacrylic acid-ethylacrylate copolymer at para.[0055] as an enterosoluble polymer) (p.8, para.[0074]), which therein constitutes a third-layer. Shinoda et al. further discloses that the sustained-release particles are employed to form a tablet preparation formulated via conventional methods (p.9, para.[0079-0080]). The fact that Shinoda et al. clearly teaches that the sustained-release particles contain at least three layers and are used to form a final tablet preparation "containing" these same three-layered particles meets Applicant's claimed requirement that the tablet "contains" three-layers, which is open-ended and allows for at least three or more layers within the final tablet preparation.

Newly amended claim 16 remains properly included in the instant rejection because Shinoda et al. expressly teaches that, "The concentration of drug, percentage and amount of polymer substance, and the like, used for the coating can be adjusted as needed in accordance with the desired speed of dissolution." (p.8, para.[0074]) It is obvious from such teachings that Shinoda et al. expressly contemplates variation in the amounts of both polymer and drug (i.e., active ingredient) employed in the disclosed sustained-release composition and specifically acknowledges that such a matter of adjusting the amounts was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease to determine the amount of active ingredient necessary, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics, such as desired dissolution time, plasma concentrations, duration of action, etc., toxicology profiles of the particular compound employed,

schedule of administration, etc. Thus, the amounts that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

In addition, the concentration of the polymer and/or active ingredient(s) is a result-effective variable, i.e., a variable that achieves a recognized result (i.e., wherein the polymer is employed as a binding agent and the active tamsulosin agent is employed for its BPH treating efficacy, as disclosed by Shinoda et al.) and, therefore, the determination of the optimum workable range of concentrations would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). Please see MPEP §2144.05[R-2](II)(A) and In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.").

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Shinoda fails to disclose that the drug layered onto the core is homogenous with the binder (such as, e.g., hydroxypropyl methylcellulose) as required by the instantly claimed invention. Applicant further alleges that Shinoda fails to teach that the drug containing layer contains a hydrophilic polymer. Applicant asserts that the formulation in Shinoda is a quick-disintegrating tablet for use in the buccal cavity that comprises sustained-release particles, whereas the instantly claimed invention is a sustained-release three-layer containing tablet, which is different. Still further, Applicant opines that the tabletting process can be performed after mixing the sustained-release particles with additives and then tabletting the mixture, which allegedly results in a formulation wherein sustained-release particles are dispersed in additives.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant opines that Shinoda fails to disclose that the drug layered onto the core is homogenous with the binder (such as, e.g., hydroxypropyl methylcellulose) as required by the instantly claimed invention. This is unpersuasive because there is no requirement in the instant claims that the "mixture" of the drug layered onto the sustained-release core is a "homogenous" mixture of the drug with the hydroxypropyl methylcellulose binder. Furthermore, the instant specification fails to define the term "mixture" as used in the instant claims to require homogeneity of the two elements comprising the mixture of the instant claims. Absent such a description in the claims of this alleged "homogeneity" of the mixture and/or any definition provided in the instant specification to direct the interpretation of the term "mixture" as necessarily requiring homogeneity, the fact that Shinoda et al. teaches that the sustained-release particles are formulated by layering the drug onto a core particle (i.e., commercial crystalline cellulose particles, crystalline lactose, granular sugar, sodium chloride, silicon dioxide, etc.) using a binder such as hydroxypropyl methylcellulose (i.e., which meets Applicant's claimed "polymer having erosion and swelling property in mammalian intestinal secretions" as recited in instant claims 1 and 3-6) (see, e.g., p.8, para.[0074]) is understood to meet Applicant's newly added claim limitation directed to the sustained-release core comprising "a mixture of" an active ingredient and a polymer having erosion and swelling properties in mammalian intestinal secretions because the interaction of the active drug (layered onto a core particle) with the applied binder (i.e., hydroxypropyl methylcellulose) at the interface of the two components creates a molecular "mixture" of the two elements, absent factual evidence to the contrary.

Secondly, Applicant alleges that Shinoda fail to teach that the drug containing layer contains a hydrophilic polymer. This is unpersuasive because Shinoda et al. discloses that a polymer substance with drug may be layered onto the particles to make a sustained release particle, wherein Shinoda et al. teaches that substances, such as, inter alia, polyvinyl alcohol may be mixed with the polymer components (i.e.,

which meets Applicant's part (c) of the claimed formulation, wherein polyvinyl alcohol is the hydrophilic polymer for film coating; p.6, para.[0057]) and the particles may then be given enterosoluble function by coating with an enterosoluble polymer base as necessary (of which Shinoda et al. explicitly teaches methacrylic acid-ethylacrylate copolymer at para.[0055] as an enterosoluble polymer) (p.8, para.[0074]). This is a clear teaching of the incorporation of a hydrophilic polymer into the drug-containing layer as required by the instant claims, absent factual evidence to the contrary and/or any substantive remarks directed to what specific elements of the instantly claimed invention Applicant asserts are lacking from the cited teachings of Shinoda et al.

Thirdly, Applicant asserts that the formulation in Shinoda is a quick-disintegrating tablet for use in the buccal cavity that comprises sustained-release particles, whereas the instantly claimed invention is a sustained-release three-layer containing tablet, which is different. This is unpersuasive. Shinoda et al. very clearly describes the formulation of sustained-release particles comprising identical elements to those instantly claimed that are used to form quick-disintegrating tablets for use in the buccal cavity. The fact that the final product of Shinoda et al. is described as a "quick-disintegrating tablet" still meets Applicant's limitation directed to a "sustained-release formulation" as instantly claimed because the tablet would necessarily release its active components over a defined period of time, which would clearly amount to "sustained" release over this limited period of time, absent factual evidence to the contrary and/or any specific definition provided by Applicant as to the desired amount of release sustained over a particular period of time. Furthermore, it is clear from the explanation supra that the formulation of Shinoda et al. constitutes a "three-layer containing tablet" as required by the instant claims because the sustained-release particles contain at least three layers and are used to form a final tablet preparation "containing" these same three-layered particles. Note also that the phrase “three-layer containing tablet” simply requires that the tablet contain three-layers therein, and, thus, the "three-layer" nature of the sustained-release particles is clear evidence that the tablet, as a whole, contains at least three layers

therein due to the presence of these layered particles, absent factual evidence to the contrary and further absent any description or requirement as to the specific structural configuration and/or arrangement of the layers.

Fourthly, and lastly, Applicant opines that the tabletting process can be performed after mixing the sustained-release particles with additives and then tabletting the mixture, which allegedly results in a formulation wherein the sustained-release particles are dispersed in additives. This is also unpersuasive. Applicant references para.[0079-0080] to support his position that additives must be added to provide the tablet, but neglects to acknowledge that the addition of additive components to the mixture to be tabletted is but one exemplary method of tabletting and is not per se required to formulate the tablets of Shinoda et al. This is further evidenced by the fact that Shinoda et al. explicitly defines the term "tabletting" as conventional methods, wherein there are no particular restrictions as long as it is a method by which the shape of a tablet is obtained under at least the minimum pressure necessary to retain the shape of a tablet. See para.[0080], p.9, of Shinoda et al. Thus, there is absolutely no requirement that "additives" be applied to the tabletted mixture to form compositions according to the invention. Even if, arguendo, such additives were required (which the Examiner does not concede), Applicant is reminded that his claims are defined using the transitional phrase "comprising", which is open claim language and allows for the use of other components with the active agents recited in the present claims. See MPEP §2111.03[R-2]. Thus, the present claims do not patentably exclude the use of additional elements, such as additives, in the final sustained-release formulation as alleged by Applicant.

For these reasons supra, and those previously made of record at p.5-8 of the Office Action dated August 18, 2010, rejection of claims 1-16 is proper.

Conclusion

Rejection of claims 1-16 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds Draper whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1614

January 19, 2011